

7/22/05

**PATENTS** 

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant:** 

Eugenio Cefali

Serial No.:

09/470,603

Filing Date:

22 December 1999

**Docket Number:** 

50454-56101USCIP3

Title:

ACID

NICOTINIC

**COMPOSITIONS** 

**FOR TREATING** 

HYPERLIPIDEMIA AND RELATED METHODS THEREFOR

**Art Unit:** 

1615 Examiner:

Robert M. Joynes

Date:

18 July 2005

Attn: Petitions Attorney Frances Hicks (517) 272-3218) Office of Petitions

Madison Building (West), 600 Dulany Street

Mail Stop 313(c)

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

### TRANSMITTAL LETTER

Sir:

Enclosed herewith for filing in connection with the above-referenced patent application, please find the following documents:

- 1) Petition to Expunge Information under 37 CFR §1.59;
- 2) Copy of Notice of Allowance dated 6 June 2005;
- 3) Copy of Supplemental Information Disclosure Statement sent 24 January 2005;
- 4) Letter dated 14 June from Bruce M. Kisliuk, Director of Technology Center 1600 re: Dismissal of Petition to Expunge filed 24 January 2005; and
- 5) Return Postcard.

If there are any questions, please contact applicants undersigned attorney by telephone at

(954) 331-3825.

Respectfully submitted,

aren J Messick

Attorney for Applicants Registration No. 46,256

Kos Pharmaceuticals, Inc. 2200 North Commerce Parkway Suite 300 Weston, FL 33326

Fax:

Phone 954.331.3825 954.331.3867

120/05

**CERTIFICATION UNDER 37 C.F.R., §1.10** 

I hereby certify that the attached papers are being deposited with the United States Postal service as: Express Mail Post Office to Addressee" Service under 37 C.F.R. §1.10 on 7/20/20 and is addressed to Commissioner for Patents, No. 100 and 1

P.O. Box 1450, Alexandria, VA 22313-1450.

*955 246 246 U*S Express Mail Label Number

Jared G. Silberhorn





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PETITION TO EXPUNGE INFORMATION UNDER 37 C.F.R. § 1.59

Sir:

As a Notice of Allowance (copy enclosed) has issued in connection with the above-referenced patent application, applicants respectfully petition the Commissioner to expunge the materials identified on the Supplemental Information Disclosure Statement sent on 24 January 2005 (copy enclosed) as "subject to protective order" if, after Examiner's consideration, any of the materials are found not to be important in deciding whether to allow the application.

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## **FEES**

The requisite fees for this Petition were paid with the original Petition to Expunge. In a letter dated 14 June 2005 from Bruce M. Kisliuk, Director of Technology Center 1600 (copy enclosed), no additional fees are due with this new Petition. However, the Commissioner is hereby authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 50-2543.

Applicants' undersigned attorney may be reached by telephone at (954) 331-3825.

All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

Karen Messick

Attorney for Applicants Registration No. 46,256

Kos Pharmaceuticals, Inc. 2200 North Commerce Parkway Suite 300 Weston, FL 33326

Phone 954.331.3825 Fax: 954.331.3867

Date: 7/20/05

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450

# NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

Karen J Messick Esq c/o KOS Pharmaceuticals Inc 1001 Brickell Bay Drive 25th Floor

Miami, FL 33133

06/06/2005

KOS PHARMAGAL DEPT.

BY:

ONTE:

EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/06/2005

		Ok.		
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470.603	12/22/1999	David J. Bova	20720-103793	6359

TITLE OF INVENTION: HYDROPHOBIC COMPONENT FREE SUSTAINED RELEASE NICOTINIC ACID COMPOSITIONS FOR TREATING HYPERLIPIDEMIA AND RELATED METHODS THEREFOR

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$70	\$0	\$70	09/06/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED</u>. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

a VE	PE			TRANSMITTAL		
Complete and send th	is form, together with	applicable fee	(s), to: <u>M</u>	P O Roy 1450	Patents	,
AR.	71 Am 3		17	Alexandria, Virginax (703) 746-4000		
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759	90 06/06/2005			have its own certificate	of mailing or transmission.  ificate of Mailing or Trans	
Karen J Messick I c/o KOS Pharmace 1001 Brickell Bay I	uticals Inc				s Fee(s) Transmittal is being ith sufficient postage for fire Stop ISSUE FEE address TO (703) 746-4000, on the d	st class mail in an envelope above, or being facsimile late indicated below.
25th Floor Miami, FL 33133				JARED	G. SILBERH	CI (Depositor's name)
Miami, FL 33133						(Signature)
				7	120/25	(Date)
APPLICATION NO.	FILING DATE	F	IRST NAME	) INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
	12/22/1900		David .	I. Bova	20720-103793	6359
TITLE OF INVENTION: I AND RELATED METHOD	HYDROPHOBIC COMPON OS THEREFOR	IENT FREE SUST	AINED REI	LEASE NICOTINIC ACID CO	OMPOSITIONS FOR TREA	
APPLN. TYPE	SMALL ENTITY	ISSUE FE	E	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$70		\$0	\$70	09/06/2005
	AINER	ART UN	IT	CLASS-SUBCLASS	]	
	CASEY SHEA	1615		424-400000		
1. Change of correspondence CFR 1.363).  Change of correspon Address form PTO/SB/	dence address or indication of "F dence address (or Change of 122) attached. ation (or "Fee Address" Indic or more recent) attached. Us	Correspondence	(1) the na or agents (2) the na registered	nting on the patent front page, is ames of up to 3 registered pate OR, alternatively, ame of a single firm (having as if attorney or agent) and the nar- red patent attorneys or agents. It mame will be printed.	a member a	y J. Hessich, E
	D RESIDENCE DATA TO	BE PRINTED ON	THE PATEN	IT (print or type)	· · · · · · · · · · · · · · · · · · ·	document has been filed for
PLEASE NOTE: Unles	ss an assignee is identified t in 37 CFR 3.11. Completion	below, no assignee n of this form is NO	data will ap T a substitut	e for filing an assignment.	nee is identified below, the	document has seen meet to
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KOS PHA	2-14C=STICALS	5, 1,2C.	7(1	AMI, FLORID	A USA	
	ate assignee category or categ	ories (will not be p	rinted on the	patent): 🔲 Individual 🗹	Corporation or other private	group entity Government
4a. The fellowing fee(s) at		4	b. Payment o	of Fee(s):		
Issue Fee			A chec	k in the amount of the fee(s) is	enclosed.	
	small entity discount permi	tted)	Payme	nt by credit card. Form PTO-20	38 is attached.	or credit any overpayment, to
Advance Order - #	of Copies		The D Deposit A	irector is hereby authorized by count Number	(enclose an extr	a copy of this form).
	us (from status indicated abo		<b>□</b> b. Арр	licant is no longer claiming SM	ALL ENTITY status. See 37	CFR 1.27(g)(2).
The Director of the USPT NOTE: The Issue Fee and interest as shown by the r	SMALL ANTITY status. See O is requested to apply the I I Publication Fee (if required ecords of the United States P	ssue Fee and Public ) will not be accept atent and Trademar	ation Fee (if ed from any k Office.	any) or to re-apply any previous one other than the applicant; a n	usly paid issue fee to the app egistered attorney or agent; o	lication identified above.  or the assignee or other party in
	18/1/			Date	7/20/05 on No. 46, 256	
Authorized Signature	Wall S. H	Essich		Registrati	on No. 46, 256	<u> </u>

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete submitting the complete application form to the USPTO to process) this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

ATTY DOCKET NO. APPLICATION NO. FORM PTO 1449 (modified) 09/470,603 50454-56101USCIP3 APPLICANT U.S. DEPARTMENT OF COM PATENT AND TRADEMARIS OFFICE Eugenio Cefali GROUP FILING DATE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary) 1615 31 October 1997 U.S. PATENT DOCUMENTS FILING DATE DOCUMENT \*EXAMINER IF APPROPRIATE DATE NAME CLASS SUBCLASS NUMBER INITIAL FOREIGN PATENT DOCUMENTS TRANSLATION YES/NO/ DOCUMENT OR ABSTRACT COUNTRY CLASS SUBCLASS DATE NUMBER OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.) Expert Report of Cheryl D. Blume, Ph.D. (January 27, 2004) - Subject to Protective Order Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version] 2 - Subject to Protective Order Rebuttal Expert Report of Dr. Sergio Fazio (April 2, 2004) 3 - Subject to Protective Order **Expert Report of Dr. Sergio Fazio Regarding** 4 U.S. Patent No. 6,676,967 (August 17, 2004) - Subject to Protective Order Expert Report of Don W. Martens (February 6, 2004) [Redacted Version] 5 - Subject to Protective Order 6 **Expert Report of Don W. Martens Regarding** U.S. Patent No. 6,676,967 (August 20, 2004) [Redacted Version] - Subject to Protective Order Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version] 7 - Subject to Protective Order Expert Report of Dr. Joseph R. Robinson Regarding 8 U.S. Patent No. 6,676,967 (August 18, 2004) - Subject to Protective Order Rebuttal Expert Report of Thomas S. Foster, Pharm.D. (April 2, 2004) 9

- Subject to Protective Order

<i>i</i> ————————————————————————————————————	10	Debut LD
	'0	Acoustic Expert Report of Thomas S. Poster, Fliarm.D.
	1	Regarding The '967 Patent (October 4, 2004)
		- Subject to Protective Order
	11	Rebuttal Expert Report of James W. McGinity, Ph.D. (April 2, 2004)
		- Subject to Protective Order
		- Subject to Protective Order
	12	Supplemental Rebuttal Expert Report of James W. McGinity, Ph.D. (August 18, 2004)
		- Subject to Protective Order
	13	Rebuttal Expert Report of James W. McGinity, Ph.D.
J	]	Regarding The '967 Patent (September 30, 2004)
	İ	- Subject to Protective Order
	14	Expert Report of Mark E. McGovern, M.D. (February 6, 2004)
		- Subject to Protective Order
	15	Expert Report of Mark E. McGovern, M.D. (August 20, 2004)
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	16	Expert Report of Frank M. Sacks, M.D. (April 2, 2004)
		- Subject to Protective Order
	17	Expert Report of Frank M. Sacks, M.D. (August 20, 2004)
		- Subject to Protective Order
	18	Rebuttal Expert Report of Mary Ann Tucker, Esq. (April 2, 2004)
		- Subject to Protective Order
	19	Debuttel Francis Devent CM A CD 1 N
	13	Rebuttal Expert Report of Mary Ann Tucker, Esq.
		Regarding The '967 Patent (October 1, 2004)
		- Subject to Protective Order
	20	Carl J. Lavie, et al., Marked Benefit with Sustained-Release Niacin Therapy in Patients
		with Alsolated@ Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary
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	21	Excernts from the 1003 2000 and 2002 editions of the Dhariniant Data Data
		Excerpts from the 1993, 2000, and 2002 editions of the Physician's Desk Reference
	22	Niggin: Double-edged Sword for Lowering Chalactered Tarks II.
		Niacin: Double-edged Sword for Lowering Cholesterol, Tufts University Diet &
ļ		Nutritional Letter (Tufts Univ., Boston, MA), August 1994, Vol. 12, issue 6
	23	Lorger MI and III. and DD D. T. T. C. T. C
	23	Larsen, ML and Illingworth, DR, Drug Treatment of Dyslipoproteinemia, Med Clin N
		Am., 78:225-245 (1994)
j	24	Lavie, Letter to Editor, JAMA 1994; 272:513-515
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	25	Keenan, Letter to Editor, JAMA 1994; 272:513-515
	26	Shields & Beckmann, Letter to Editor, JAMA 1994; 272:513-515
	27	Thomas N. Tozer, Clinical Pharmacokinetics Concepts and Applications (3d ed. 1995) at Chapter 9, p. 120
	28	Excerpts from the United States Pharmacopeia (1995)
	29	Morgan & Capuzzi Abstract, Safe and Effective Treatment of Dyslipidemia by Niaspan, a New Sustained-Release Niacin, Clinical Pharmacology & Therapeutics (February 1996)
·	30	Morgan & Capuzzi Article, Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial, J. Cardiovasc. Pharmacol. Therapeut. 1(3):195-202 (July 1996)
	31	Capuzzi DM, et al., Efficacy and Safety of An Extended-Release Niacin (Niaspan): A Long-Term Study, Am J Cardiol. 1998;82:74U-81U
	32	Guyton JR, Advances in Dyslipidemia: Discussion Session II, Am J Cardiol, 1998: 82(12A): 85U-86U
	33	Knopp RH, et al., Equivalent Efficacy of a Time-Release Form of Niacin (Niaspan) Given Once-a-Night Versus Plain Niacin in the Management of Hyperlipidemia, Metabolism 47:1097-1104 (1998)
	34	American Diabetes Association: Management of Dyslipidemia in Adults with Diabetes, Diabetes Care 21:179-182, 1998
	35	Elam MB, et al., Effect of Niacin on Lipid and Lipoprotein Levels and Glycemic Control in Patients With Diabetes and Peripheral Arterial Disease, JAMA: 2000; 284:1263-1270
	36	Kesala R, et al., Niacin (N) vs. Niaspan (NS) Treatment of the Atherogenic Lipid Profile (ALP; Small, Dense LDL, HDL2, HDLc and Triglycerides) and Lp(a) in Diabetic Patients (DP), Diabetes 49 (suppl. 1): A268 at 1114-P (June 2000)
	37	2001 NCEP Report at VI-11, Table VI.2-3
	38	Wang, W. et al., Effect of Nicotinic Acid Administration on Hepatic Very Low Density Lipoprotein-Triglyceride Production, Am J Physiol Endocrinol Metab., 280:E540-E547 (2001)

EXAMINER		DATE CONSIDERED				
	50	Sample Kos Clinical Trial Investigator's Statement - Subject to Protective Order				
	49	Sample Kos Clinical Trial Medical Consent Form - Subject to Protective Order				
	48	American Diabetes Association: Dyslipidemia Management in Adults with Diabetes, Diabetes Care 27:S68-S71, 2004				
	47	CDER Guidance for Industry, Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations (March 2003)				
	46	Meyers CD, et al., Varying Cost and Free Nicotinic Acid Content in Over-the-Counter Niacin Preparations for Dyslipidemia, Ann Intern Med. 2003; 139:996-1002				
	45	Pan J, et al., Extended-Release Niacin Treatment of the Atherogenic Lipid Profile and Lipoprotein(a) in Diabetes, Metabolism 51:1120-1127 (2002)				
	44	Pan J, et al., Niacin Treatment of the Atherogenic Lipid Profile and Lp(a) in Diabetes, Diabetes, Obesity and Metabolism 4:255-261 (2002)				
	43	American Diabetes Association: Management of Dyslipidemia in Adults with Diabetes, Diabetes Care 25:S74-S77, 2002				
	42	Grundy SM, et al., Efficacy, Safety, and Tolerability of Once-Daily Niacin for the Treatment of Dyslipidemia Associated with Type 2 Diabetes. Arch Intern Med. 2002; 162: 1568-1576				
	41	Meadows M., Serious Liver Injury: Leading Reason for Drug Removals, Restrictions, FDA Consumer Magazione, May-June 2001; http://www.fda.gov/fdac/features/2001/301_liver.html				
	40	Tavintharan S and Kashyap M, <i>The Benefits of Niacin in Atherosclerosis</i> , Curr Athero. Reports 2001; 3:74-82				
	39	Smith SC, et al., AHA/ACC Guidelines for Preventing Heart Attack and Death in Patients with Atherosclerotic Cardiovascular Disease: 2001 Update. AHA/ACC Scientific Statement, 1577-79				





Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450

Alexandria, VA 22313-1450 www.uspto.gov

JUN 14 2005

KAREN J. MESSICK, ESQ. C/O KOS PHARMACEUTICALS, INC. 1001 BRICKELL BAY DRIVE, 25<sup>TH</sup> FLOOR MIAMI, FL, 33133

In re Application of David Bova et al

Serial No.: 09/470,603 Filed: December 22, 1999

Attorney Docket No.: 50454-56101US

: PETITION DECISION

This is a response to the petition under 37 CFR 1.59(b), filed March 10, 2005, to expunge information from the above identified application.

Petitioner requests that documents submitted in an Information Disclosure Statement (IDS), filed March 10, 2005, be expunged from the record. Petitioner states either: (A) that the information contains trade secret material, proprietary material and/or material that is subject to a protective order which has not been made public; or (B) that the information submitted was unintentionally submitted and the failure to obtain its return would cause irreparable harm to the party who submitted the information or to the party in interest on whose behalf the information was submitted, and the information has not otherwise been made public. The petition fee set forth in 37 CFR 1.17(h) has been paid.

The decision on the petition is held in abeyance. It is noted that a concurrently file petition to withdraw this application from issue has been granted, thus reopening prosecution for consideration of the IDS containing confidential material. Therefore, prosecution on the merits is not closed. Accordingly, it is not appropriate to make a final determination of whether or not the material requested to be expunged is "material," with "materiality" being defined as any information which the examiner considers as being important to a determination of patentability of the claims.

During prosecution on the merits, the examiner will determine whether or not the identified document is considered to be "material." If the information is not considered by the examiner to be material, the information will be returned to applicant.

The petition to expunge is at this time **DISMISSED**.

Upon termination of prosecution of the application applicants should submit a renewed petition to expunge the proprietary material. No fee will be due for the renewed petition.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number 571-273-8300.

Bruce M. Kisliuk

Director, Technology Center 1600